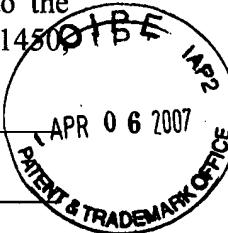


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on April 4, 2007


Glenn P. Ladwig, Patent Attorney



INFORMATION DISCLOSURE STATEMENT
Examining Group 1632
Patent Application
Docket No. USF-T192XC1
Serial No. 10/544,145

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : (Not yet assigned)
Art Unit : 1632
Applicant : Shyam S. Mohapatra
Serial No. : 10/544,145
Filed : August 2, 2005
For : Chitosan-Microparticles for IFN Gene Delivery

MS AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

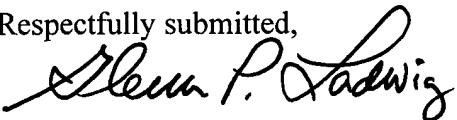
INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed. However, the applicant has not submitted copies of the U.S. patents or published U.S. applications cited on attached Form PTO/SB/08 pursuant to 37 C.F.R. §1.98(a)(2)(ii).

The applicant respectfully asserts that the substantive provisions of 37 C.F.R. §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



Glenn P. Ladwig
Patent Attorney
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GPL/mv

Attachments: Form PTO/SB/08 (7 pages); copies of some references cited therein



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Application Number	10/544,145
Sheet	1	of	7	Filing Date	August 2, 2005
				First Named Inventor	Shyam S. Mohapatra
				Art Unit	1632
				Examiner Name	
				Attorney Docket Number	USF-T192XC1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	U1	US-6,489,306 B2	12-03-2002	Mohapatra et al.	All
	U2	US-5,527,538	06-18-1996	Baldeschwieler	All
	U3	US-5,441,745	08-15-1995	Presant et al.	All
	U4	US-5,435,989	07-25-1995	Presant et al.	All
	U5	US-5,264,618	11-23-1993	Felgner et al.	All
	U6	US-5,019,369	05-28-1991	Presant et al.	All
	U7	US-4,897,355	01-30-1990	Eppstein et al.	All
	U8	US-2006/0239971 A1	10-26-2006	Mohapatra et al.	
	U9	US-2005/0159385 A1	07-21-2005	Mohapatra	All

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)			
	F1	WO 03/028759 A1	04-10-2003	Univ of South Florida	All
	F2	WO 02/34287 A2	05-02-2002	Pharmexa A/S	All
	F3	WO 99/36089 A1	07-22-1999	Johns Hopkins Univ	All
	F4	WO 97/45442 A1	12-04-1997	Imperial College Sci Tech Med.	All
	F5	WO 97/20576 A1	06-12-1997	Danbiosyst UK Lmted	All
	F6	WO 95/02698 A1	01-26-1995	Life Tech., Inc.	All
	F7	WO 91/15501 A1	10-17-1991	Yale University	All

Examiner Signature	Date Considered
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Sheet	2	of	7	Filing Date	August 2, 2005
				First Named Inventor	Shyam S. Mohapatra
				Art Unit	1632
				Examiner Name	
				Attorney Docket Number	USF-T192XC1

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		Number - Kind Code ² (if known)			
U10	US-2005/0266093 A1		12-01-2005	Mohapatra	All
U11	US-2005/0158327 A1		07-21-2005	Mohapatra et al.	All
U12	US-2004/0175384 A1		09-09-2004	Mohapatra et al.	All
U13	US-2004/0009152 A1		01-15-2004	Mohapatra et al.	All
U14	US-2003/0198624 A1		10-23-2003	Mohapatra et al.	All
U15	US-2003/0068333 A1		04-10-2003	Mohapatra et al.	All
U16	US-10/655,873		09-05-2003	Mohapatra et al. (patent application)	All
U					

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F					
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<p>Substitute for form 1449B/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				Complete if Known	
Sheet	3	of	7	Application Number	10/544,145
				Filing Date	August 2, 2005
				First Named Inventor	Shyam S. Mohapatra
				Group Art Unit	1632
				Examiner Name	
				Attorney Docket Number	USF-T192XC1

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
	R1	Accession No: NM_000639, NCBI database, "Homo sapiens Fas ligand (TNF superfamily, member 6) (FASLG, mRNA" August 1, 2005.				
	R2	BEHERA, A.K. et al. "2'-5' oligoadenylate synthetase plays a critical role in interferon- γ inhibition of respiratory syncytial virus infection of human epithelial cells" <i>J Biol Chem</i> , 2002, 277:25601-25608.				
	R3	BEHERA, A.K. et al. "Adenovirus-mediated interferon γ gene therapy for allergic asthma: involvement of interleukin 12 and STAT4 signaling" <i>Human Gene Therapy</i> , 2002, 1697-1709.				
	R4	BIVAS-BENITA, M. et al. "Pulmonary delivery of chitosan-DNA nanoparticles enhances the immunogenicity of a DNA vaccine encoding HLA-A*0201-restricted T-cell epitopes of <i>Mycobacterium tuberculosis</i> " <i>Vaccine</i> , 2004, 22:1609-1615.				
	R5	BORASCHI, D. et al. "Interferons inhibit LTC ₄ production in murine macrophages" <i>J Immunol</i> , 1987, 138:4341-4346.				
	R6	BROOKING, J. et al. "Transport of nanoparticles across the rat nasal mucosa" <i>J Drug Target</i> , 2001, 9:267-279.				
	R7	DAINES, M.O. and HERSHY, G.K. "A novel mechanism by which interferon- γ can regulate interleukin (IL)-13 responses" <i>J Biol Chem</i> , 2002, 277(12):10387-10393.				
	R8	DE SMEDT, S.C. et al. "Cationic polymer based gene delivery systems" <i>Pharm. Res.</i> , 2000, 17:113-126.				
	R9	DOW, S.W. et al. "Systemic and local interferon γ gene delivery to the lungs for treatment of allergen-induced airway hyperresponsiveness in mice" <i>Hum Gene Ther</i> , 1999, 10:1905-1914.				
	R10	ERBACHER, P. et al. "Chitosan-based vector/DNA complexes for gene delivery: biophysical characteristics and transfection ability" <i>Pharm Res</i> , 1998, 15:1332-1339.				
	R11	FILIPović-GRČić, J. et al. "Mucoadhesive chitosan-coated liposomes: characteristics and stability" <i>J Microencapsul</i> , 2001, 18:3-12.				
	R12	FLAISHON, L. et al. "Cutting edge: Anti-inflammatory properties of low levels of IFN- γ " <i>J Immunol</i> , 2002, 168:3707-3711.				
	R13	FORD, J.G. et al. "IL-13 and IFN- γ : interactions in lung inflammation" <i>J Immunol</i> , 2001, 167:1769-1777.				

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
Sheet	4	of	7	Application Number	10/544,145
				Filing Date	August 2, 2005
				First Named Inventor	Shyam S. Mohapatra
				Group Art Unit	1632
				Examiner Name	
				Attorney Docket Number	USF-T192XC1

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	R14	GARNETT, M.C. "Gene-delivery systems using cationic polymers" <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 1999, 16:147-207.			
	R15	GURUJEYALAKSHMI, G. and GIRI, S.N. "Molecular mechanisms of antifibrotic effect of interferon gamma in bleomycin-mouse model of lung fibrosis: Downregulation of TGF- β and procollagen I and III gene expression" <i>Exp Lung Res</i> , 1995, 21:791-808.			
	R16	HAMAJIMA, K. et al. "Chitin micro-particles (CMP): A useful adjuvant for inducing viral specific immunity when delivered intranasally with an HIV-DNA vaccine" <i>Viral Immunology</i> , 2003, 16:541-547.			
	R17	HAYES, M.P. et al. "Regulation of interleukin-12 expression in human monocytes: Selective priming by interferon- γ of lipopolysaccharide-inducible p35 and p40 genes" <i>Blood</i> , 1995, 86:646-650.			
	R18	HELLERMAN, G. et al. "Chitosan IFN-gamma-gene nanosphere (CIN) therapy for allergic asthma: Modulation of specific T-cell and dendritic cell responses" <i>J. Allergy Clin Immunol.</i> , 2003, 111:S265, abstract no. 791.			
	R19	HELLERMANN, G.R. et al. "Mechanism of cigarette smoke condensate-induced acute inflammatory response in human bronchial epithelial cells" <i>Resp. Res.</i> , 2002, 3:22-30.			
	R20	KABANOV, A.V. "Taking polycation gene delivery systems from <i>in vitro</i> to <i>in vivo</i> " <i>Pharm. Sci. Tech. Today</i> , 1999, 2:365-372.			
	R21	KIM, Y.H. et al. "Structural characteristics of size-controlled self-aggregates of deoxycholic acid-modified chitosan and their application as a DNA delivery carrier" <i>Bioconjug Chem</i> , 2001, 12:932-938.			
	R22	KOLTOVER, I. et al. "An inverted hexagonal phase of cationic liposome-DNA complexes related to DNA release and delivery" <i>Science</i> , 1998, 281:78-81.			
	R23	KONG, X. et al. "Chitosan IFN-gamma-gene nanoparticle (CIN) therapy for allergic asthma in mice involves STAT4 signaling pathway" <i>J. Allergy Clin Immunol.</i> , 2003, 111:S354, abstract no. 1144.			
	R24	KOTZÉ, A.F. et al. "Enhancement of paracellular drug transport with highly quaternized N-trimethyl chitosan chloride in neutral environments: In vitro evaluation in intestinal epithelial cells (Caco-2)" <i>J Pharm Sci</i> , 1999, 88:253-257.			
	R25	KRASNOWSKA, M. et al. "Effect of recombinant IFN- γ on IgE-dependent leukotriene generation by peripheral blood leukocytes in patients with pollinosis and asthma" <i>Arch Immunol Ther Exp (Warsz)</i> , 2000, 48:287-292.			
	R26	KUMAR, M. et al. "Role of mucosal IFN- γ gene transfer on allergic sensitization and RSV infection" <i>J. Allergy Clin Immunol.</i> , 2002, 109:S4, abstract no. 78.			

Examiner Signature	Date Considered
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Sheet	5	of	7	Application Number	10/544,145
				Filing Date	August 2, 2005
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				Group Art Unit	1632
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	R27	KUMAR, M. et al. "Intranasal gene transfer by chitosan-DNA nanospheres protects BALB/c mice against acute respiratory syncytial virus infection" <i>Human Gene Therapy</i> , 2002, 13:1415-1425.			
	R28	KUMAR, M. et al. "IFN- γ and IL-12 plasmid DNAs as vaccine adjuvant in a murine model of grass allergy" <i>J Allergy Clin Immunol</i> , 2001, 108:402-408.			
	R29	KUMAR, M. et al. "Intranasal IFN- γ gene transfer protects BALB/c mice against respiratory syncytial virus infection" <i>Vaccine</i> , 1999, 18:558-567.			
	R30	LI, X-M. et al. "Mucosal IFN- γ gene transfer inhibits pulmonary allergic responses in mice" <i>J Immunol</i> , 1996, 157:3216-3219.			
	R31	MATSUSE, H. et al. "Recurrent respiratory syncytial virus infections in allergen-sensitized mice lead to persistent airway inflammation and hyperresponsiveness" <i>J Immunol</i> , 2000, 164:6583-6592.			
	R32	MINAGAWA, K. et al. "Direct observation of the biphasic conformational change of DNA induced by cationic polymers" <i>FEBS Lett</i> , 1991, 295:67-69.			
	R33	MINSHALL, E. et al. "Eosinophil-associated TGF- β mRNA expression and airways fibrosis in bronchial asthma" <i>Am J Respir Cell Mol Biol</i> , 1997, 17:326-333.			
	R34	MIYAZAKI, S. et al. "Chitosan and sodium alginate based bioadhesive tablets for intraoral drug delivery" <i>Biol Pharm Bull</i> , 1994, 17(5):745-747.			
	R35	MOSMANN, T.R. et al. "TH1 and TH2 cells: Different patterns of lymphokine secretion lead to different functional properties" <i>Ann Rev Immunol</i> , 1989, 7:145-173.			
	R36	MURRAY, H.W. "Current and future clinical applications of interferon-gamma in host antimicrobial defense" <i>Intensive Care Med</i> , 1996, 22(Suppl 4):S456-S461.			
	R37	MUZZARELLI, R. et al. "Reconstruction of periodontal tissue with chitosan" <i>Biomaterials</i> , 1989, 10:598-603.			
	R38	NISHIMURA, K. et al. "Immunological activity of chitin and its derivatives" <i>Vaccine</i> , 1984, 2:93-99.			
	R39	OTTERLEI, M. et al. "Characterization of binding and TNF- α -inducing ability of chitosans on monocytes: the involvement of CD14" <i>Vaccine</i> , 1994, 12:825-832.			

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	R40	PAPINEAU, A.M. et al. "Antimicrobial effect of water-soluble chitosans with high hydrostatic pressure" <i>Food Biotechnol.</i> , 1991, 5:45-57.			T ²
	R41	PIERKES, M. et al. "Decreased release of histamine and sulfidoleukotrienes by human peripheral blood leukocytes after wasp venom immunotherapy is partially due to induction of IL-10 and IFN- γ production of T cells" <i>J Allergy Clin Immunol.</i> , 1999, 103:326-332.			
	R42	REMY, J-S. et al. "Gene transfer with lipospermines and polyethylenimines" <i>Adv. Drug Deliv. Rev.</i> , 1998, 30:85-95.			
	R43	RICHARDSON, S.C. et al. "Potential of low molecular mass chitosan as a DNA delivery system: biocompatibility, body distribution and ability to complex and protect DNA" <i>Int. J. Pharm.</i> , 1999, 178:231-243.			
	R44	SINGLA, A.K. and CHAWLA, M. "Chitosan: some pharmaceutical and biological aspects—an update" <i>J Pharm Pharmacol.</i> , 2001, 53:1047-1067.			
	R45	TANG, C. et al. "Th type 1-stimulating activity of lung macrophages inhibits Th2-mediated allergic airway inflammation by an IFN- γ -dependent mechanism" <i>J Immunol.</i> , 2001, 166:1471-1481.			
	R46	THANOU, M. et al. "Quaternized chitosan oligomers as novel gene delivery vectors in epithelial cell lines" <i>Biomaterials</i> , 2002, 23:153-159.			
	R47	THIVIERGE, M. et al. "IL-13 and IL-4 up-regulate cysteinyl leukotriene 1 receptor expression in human monocytes and macrophages" <i>J Immunol.</i> , 2001, 167:2855-2860.			
	R48	UMETSU, D.T. et al. "T _{H1} and T _{H2} CD4 $^{+}$ cells in human allergic diseases" <i>J Allergy Clin Immunol.</i> , 1997, 100:1-6.			
	R49	VAN DER LUBBEN, I.M. et al. "Chitosan and its derivatives in mucosal drug and vaccine delivery" <i>Eur J Pharm Sci.</i> , 2001, 14:201-207.			
	R50	WROBEL, I. and COLLINS, D. "Fusion of cationic liposomes with mammalian cells occurs after endocytosis" <i>Biochem. Biophys. Acta</i> , 1995, 1235:296-304.			
	R51	YOSHIDA, M. et al. "Effect of interferon- γ on allergic airway responses in interferon- γ -deficient mice" <i>Am J Respir Crit Care Med.</i> , 2002, 166:451-456.			
	R 52	GILL, D.R. et al. "The development of gene therapy for diseases of the lung" <i>Cell. Mol. Life Sci.</i> , 2004, 61:355-368.			

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<p>Substitute for form 1449B/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p>(use as many sheets as necessary)</p>				Complete if Known	
Sheet	7	of	7	Application Number	10/544,145
				Filing Date	August 2, 2005
				First Named Inventor	Shyam S. Mohapatra
				Group Art Unit	1632
				Examiner Name	
				Attorney Docket Number	USF-T192XC1

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	R53	PERRICONE, M.A. et al. "Aerosol and lobar administration of a recombinant adenovirus to individuals with cystic fibrosis. II. Transfection efficiency in airway epithelium" <i>Human Gene Therapy</i> , 2001, 12:1383-1394.			
	R54	"Gene" from The American Heritage Dictionary of the English Language, 4 th Ed. (online), 2000 (retrieved on 2006-06-15). Retrieved from the Internet: <URL: http://dictionary.reference.com/browse/gene >.			
	R55	"Timolol Maleate" from RxList The Internet Drug Index (online), 2006 (retrieved on 2006-06-15). Retrieved from the Internet: <URL: http://www.rxlist.com/cgi/generic3/timololfs_wcp.htm >.			
	R56	"Respiratory tract" from Wikipedia (online), 2006 (retrieved on 2006-06-15). Retrieved from the Internet: <URL: http://en.wikipedia.org/wiki/Respiratory_tract >.			
	R57	RENER, X. et al. "Construction and identification of a recombinant adenovirus which expresses human interferon-γ" <i>Chinese J. Biotech.</i> , 1997, 13:1-8.			
	R58	FLOTTE, T. and LAUBE, B. "Gene therapy in cystic fibrosis" <i>Chest</i> , 2001, 120:124S-131S.			
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